

**INTEGRATIVE THERAPEUTICS INC.**NF Formulas & PhytoPharmica  
Tyler Encapsulations & Vitaline Formulas

9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 F: 503.582.0467

**ENZYMATIC THERAPY**&  
**PHYTOPHARMICA**

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 F: 888.570.6460 (Enzymatic)

P: 920.469.9099 F: 920.469.4418 (Phyto)

**ENZYMATIC THERAPY**

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December 22, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

DEC 25 2005

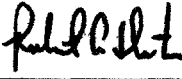
RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
B100 Energy Complex*	Improve your mood*	Thiamin (as thiamine mononitrate), Riboflavin, Niacin (as niacinamide), Vitamin B-6 (as pyridoxine hydrochloride), Folic Acid, Vitamin B-12 (as cyanocobalamin), Biotin, Pantothenic Acid (as calcium pantothenate), Choline Bitartrate, Inositol, Para-aminobenzoic acid

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

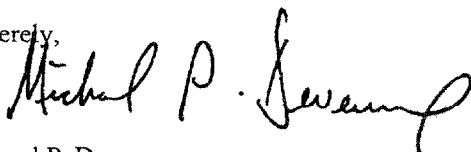
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/22/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer

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## ENZYMATIC THERAPY

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December 21, 2005

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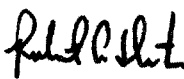
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
B100 Energy Complex*	Increase your energy*	Thiamin (as thiamine mononitrate), Riboflavin, Niacin (as niacinamide), Vitamin B-6 (as pyridoxine hydrochloride), Folic Acid, Vitamin B-12 (as cyanocobalamin), Biotin, Pantothenic Acid (as calcium pantothenate), Choline Bitartrate, Inositol, Para-aminobenzoic acid

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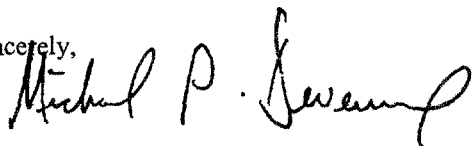
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/21/05

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Sincerely,



Michael P. Devereux  
Chief Operations Officer

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
B100 Energy Complex*	Reduce your stress*	Thiamin (as thiamine mononitrate), Riboflavin, Niacin (as niacinamide), Vitamin B-6 (as pyridoxine hydrochloride), Folic Acid, Vitamin B-12 (as cyanocobalamin), Biotin, Pantothenic Acid (as calcium pantothenate), Choline Bitartrate, Inositol, Para-aminobenzoic acid

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By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

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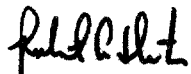
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
B100 Energy Complex*	Supports serotonin levels to resist the effects of stress*	Thiamin (as thiamine mononitrate), Riboflavin, Niacin (as niacinamide), Vitamin B-6 (as pyridoxine hydrochloride), Folic Acid, Vitamin B-12 (as cyanocobalamin), Biotin, Pantothenic Acid (as calcium pantothenate), Choline Bitartrate, Inositol, Para-aminobenzoic acid

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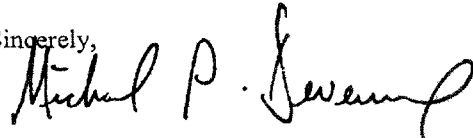
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Robert Doster

Title: Senior Vice President of Scientific Affairs

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Chief Operations Officer

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
B100 Energy Complex*	Thiamin is necessary for carbohydrate and sugar metabolism. Because of its involvement in the synthesis of acetylcholine, supplemental thiamin helps support healthy neurotransmitter balance.*	Thiamin (as thiamine mononitrate)

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By: 

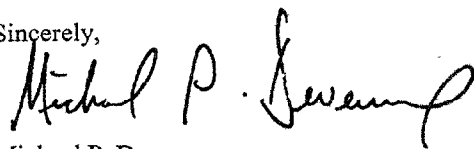
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/21/05

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Chief Operations Officer

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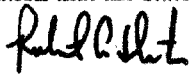
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
B100 Energy Complex*	Riboflavin is involved in the metabolism of fats, proteins, and carbohydrates. It is crucial for the production of energy.*	Riboflavin

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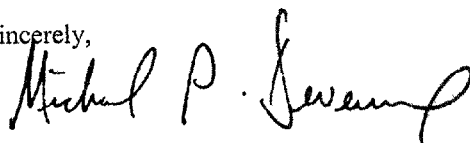
By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/21/05

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Sincerely,



Michael P. Devereux  
Chief Operations Officer



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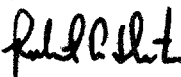
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
B100 Energy Complex*	Pyridoxine plays an important role in tryptophan metabolism, increasing the production of 5-HTP, a precursor of serotonin.*	Vitamin B-6 (as pyridoxine hydrochloride)

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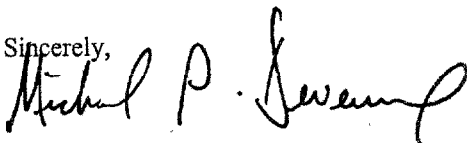
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Title: Senior Vice President of Scientific Affairs

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
B100 Energy Complex*	Supplementation can help promote a positive mood.*	Folic Acid

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/22/05

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
B100 Energy Complex*	Supplementation can reduce homocysteine, which has positive implications for serotonin levels.*	Vitamin B-12 (as cyanocobalamin)

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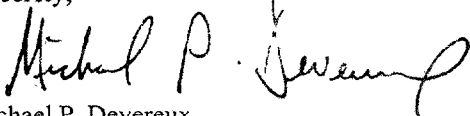
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
B100 Energy Complex*	Vitamin B12 is important for the health of nervous system cells.*	Vitamin B-12 (as cyanocobalamin)

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B100 Energy Complex*	In combination with folic acid, vitamin B12 supplementation can improve mood.*	Folic Acid, Vitamin B-12 (as cyanocobalamin)

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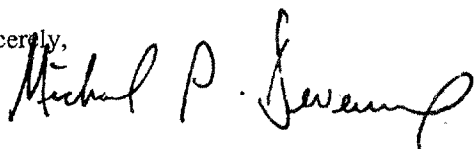
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/22/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Operations Officer



## ENZYMATIC THERAPY INCORPORATED

What **Better** feels like.™

December 22, 2005

### INTEGRATIVE THERAPEUTICS INC.™ NF Formulas • PhytoPharmica Tyler Encapsulations • Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 • F: 503.582.0467

### ENZYMATIC THERAPY™ & PHYTOPHARMICA™

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 • F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 • F: 920.469.4418 (Phyto)

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
B100 Energy Complex*	Inositol supports healthy nerve cell transmission.*	Inositol

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

Robert Doster  
Title: Senior Vice President of Scientific Affairs

Date: 12/22/05

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
B100 Energy Complex*	Inositol has also been studied for its positive effects on mood, memory, attention, and focus.*	Inositol

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

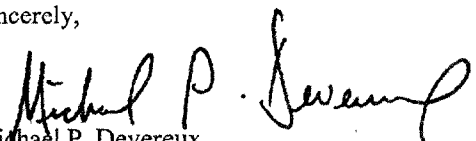
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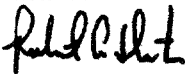
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
B100 Energy Complex*	PABA may increase oxygen uptake at the tissue level.*	Para-Aminobenzoic Acid

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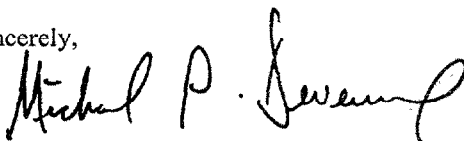
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